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| 10/700,305 | 10/31/2003 | James Kaput | Kaput-100 US | 5444 |
| 39843 | 7590 | 04/21/2008 | | |
| BELL & ASSOCIATES 201 WARREN DRIVE SAN FRANCISCO, CA 94131 | | | | |
| EXAMINER | | | | |
| SISSON, BRADLEY L | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1634 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/700,305

Applicant(s)

KAPUT, JAMES

Examiner

Bradley L. Sisson

Art Unit

1634

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 17-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4 and 17-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

1. The following is a quotation of the appropriate paragraph of 37 CFR 1.67(b) that forms the basis of the objection under this section made in this Office action:

A supplemental oath or declaration meeting the requirements of § 1.63 must be filed when a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented or when an oath or declaration submitted in accordance with § 1.53(f) after the filing of the specification and any required drawings specifically and improperly refers to an amendment which includes new matter. No new matter may be introduced into a nonprovisional application after its filing date even if a supplemental oath or declaration is filed. In proper situations, the oath or declaration here required may be made on information and belief by an applicant other than the inventor.

As a result of amendment(s) to the claim(s), the pending claim(s) no longer substantially embrace the invention as set forth in the statement of the invention and/or in the original claim(s). Accordingly, applicant is required to file a supplemental oath or declaration in response to this Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4, and 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1, the sole independent claim, is indefinite where, as a result of recent amendment, the claim now reads: "identifying previously unidentified in diet-regulated disease-associated

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polynucleotides.” (Emphasis added.) Claims 4 and 17-25, which all depend from said claim 1, fail to overcome this issue and are similarly rejected.

5. Claims 20-25 are confusing where it is stated in each of said claims that the “loci is known to encode one or more genes.” While a gene is recognized as encoding an amino acid sequence of a polypeptide, the aspect of a “coding” of and within a loci for genes is less than clear. Perhaps applicant intended to indicate that the loci comprise one or more genes.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4, and 17-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying in mice previously known nucleic acids that are associated with various diseases, does not reasonably provide enablement for the identification of “previously unidentified” diet-regulated disease-associated polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As a result of the amendment of 03 March 2008, the claims are now limited to the identification of “previously unidentified...diet-regulated disease associated polynucleotides” in rodents. The method, however, requires the matching of the isolated polynucleotides to “quantitative trait loci (QTLs) known to encode one or more genes that contribute to the development of a disease.” Such a method does not result in the identification of “previously unidentified” polynucleotides, but rather, results in confirming that which was already “known.”

8. Assuming *arguendo* that the claimed method were to be fully enabled, a point that the Office does not concede, the specification does not enable the use of the previously unidentified polynucleotide. It is not enough that the method result in a product. Rather, the specification must also teach how to use the product, once realized. While an applicant is not required to teach each and every embodiment encompassed by the claims, the specification still must fully enable the claimed invention.

9. When as here, the product is “previously unidentified,” the specification must also set forth a reproducible method by which the product is used in a method that satisfies the utility requirements of 35 USC 101. Such an enabling disclosure has not been provided.

10. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 4, and 17-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying in mice previously known nucleic acids that are associated with various diseases, does not reasonably provide enablement for the identification of “previously unidentified” diet-regulated disease-associated polynucleotides.

Conclusion

11. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/

Primary Examiner, Art Unit 1634